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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,172	07/25/2001	Oren Globerman	110/02239	7714

44909 7590 04/06/2005

FENSTER & COMPANY INTELLECTUAL PROPERTY 2002 LTD.  
C/O REED SMITH LLP  
599 LEXINGTON AVENUE, 29TH FLOOR  
NEW YORK, NY 10022-7650

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/890,172

Applicant(s)

GLOBERMAN ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-106, 110-112, 116-125, 148, 149 and 209-213 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 5, 25, 26, 29, 32, 33, 45, 47, 49, 50, 65, 67, 69, 71-77, 79, 82, 83, 87, 88, 96, 97 and 120 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims rejected are 1-4,6-24,27,28,30,31,34-44,46,48,51-64,66,68,70,78,80,81,84-86,89-95,98-106,110-112,116-119,121-125,148,149 and 209-213.

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on January 13, 2003 and March 24, 2005 have been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 212 and 213 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expanded diameter about three times the non-expanded diameter, does not reasonably provide enablement for expanded diameters much larger than about three times. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Upon review of the specification, the Examiner enablement for the full scope of the invention that includes the open ended range of at least three times the diameter of the non-expanded tube. For this reason, the Examiner asserts that the full scope of the claimed invention is not enabled.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-16, 19-24, 27, 28, 30, 31, 34, 35, 41-44, 46, 48, 51-62, 64, 66, 68, 70, 78, 80, 81, 84, 86, 90-95, 98-106, 110-112, 121-125, and 209-211 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisharodi (US 5,693,100). Pisharodi anticipates the claim language where the tube as claimed is shown in Figure 7 of Pisharodi (see also column 7, lines 27-37), the slits as claimed are between sections (34), the axial displaced extensions are the axial aligned legs of subunits (34,36), and the locking element is the screw (42) with locknut (40); see the figures, column 4, line 58 to column 5, line 46.

By looking at Figures 5 and 6 for reference, it is clear that each leg (34) produces a peak, there are two peaks shown along each pair of legs and there is a portion radially inward of the peaks in this axially compressed configuration. This same structure would also be present in the embodiment of Figure 7 where the axially compressed configuration is not shown. For this reason, the Examiner asserts that the claim language is fully met.

Regarding claim 9, the slits between the legs are perpendicular or not parallel to the longitudinal axis.

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Regarding claim 11, slits along the axis are of a different length than the slit between the legs.

Regarding claim 30, Pisharodi has two segments along the longitudinal axis.

Regarding claims 56, 59, 64, and 113, the cross-section claimed can be taken at an angle across any part of the device such that the claim language is fully met to the extent it can be given patentable weight.

Regarding claim 81, see Figure 6 or 7 where the bottom subunits (36) are connected at their tops.

Regarding claim 98-102, the claim language does not require that the deformation will only take place at the values set forth herein, and thus, the claim language is read on by what is disclosed by Pisharodi.

Regarding claims 209 and 210, the transaxial direction is the radial direction and all 16 extend in the same transaxial or radial direction.

Claims 1, 125, 148, and 149 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (US 3,846,846) where the extensions as claimed are the leading ends 9a of Fischer of the three axially aligned expansion elements of Figures 1 and 2; see also column 3, line 40 to column 4, line 54. With an analogous interpretation of the claim language, Fischer also meets the new added claim limitations.

With regard to claims 1 and 148, the locking element as claimed is the made up of the nut (6), rod (7), and/or expander portion (8) of Fischer.

With regard to claim 125 and 149, since the Fischer device can be made of titanium (an extremely hard metal) and since the language "spinal forces applied in a

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direction radial to the spacer" is construed as quite broad, the Examiner asserts that the claim language is fully met by Fischer.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-40, 63, 104, 105, 113-115, and 212-213 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) alone.

Regarding claims 36-40, Pisharodi discloses a rectangular and truncated triangle cross-sectional profile in the two embodiments disclosed; see the Figures. But Pisharodi fails to disclose the use of the cross-sectional profiles claimed. However, since Pisharodi discloses different profiles, it is the Examiner's position that it would have been considered prima facie obvious to use other profiles including those claimed because it is not clear that the different profiles would result in a substantially different operation or function from that of Pisharodi.

Pisharodi meets the claim language except for the elliptical cross-sectioned tube (claim 63). However, since Pisharodi discloses at least two cross-sectional shapes (i.e. rectangular and octagonal), it is the Examiner's position that it would have been considered prima facie obvious to use other profiles in Pisharodi in order to accommodate other numbers of leg projections.

Regarding claims 104-105 and 113-115, since the diameter of expansion can be incrementally varied, it follows that small fractions over the unexpanded diameter are possible with Pisharodi's device such that the claimed diameter is clearly obvious over Pisharodi alone.

With regard to claim 212-213, Pisharodi fails to disclose the relative diameters of the expanded and non-expanded diameters as claimed. However, the mere designation of the size or proportion is not considered patentable because Pisharodi appears to disclose something at least near the claimed range and it would have been obvious to make the Pisharodi's device expand more or less depending upon the size and needs of the particular patient. It is noted that Pisharodi's device is adjustable indicating that it would have been obvious to adjust it to the size of the patient.

*In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 85 and 89 are rejected under 35 U.S.C. 102(b) as anticipated by Pisharodi (US 5,693,100) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pisharodi (US 5,693,100) alone. Pisharodi fails to disclose the process of making step claimed of annealing the device. However, the Examiner asserts that such a process step would not result in a different product from that of Pisharodi; see MPEP 2113, which is incorporated herein by reference thereto.



Alternatively, if annealing does result in a different product, it appears to only result in a slightly different product such that the claimed invention would have been considered at least clearly obvious to an ordinary artisan.

Claims 17, 18, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) in view of Pisharodi (US 5,123,926).

Regarding claims 17, 18, and 119, Pisharodi discloses an expandable spacer but lacks the teaching of spurs on the spacer as claim. Pisharodi teaches of an artificial spine prosthesis with spurs (Fig. 3, Ref. Num. 8) to hold the prosthesis within the intervertebral disk space. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Pisharodi to have spurs on the outside of the spacer to better hold it in place.

Claims 116-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) in view of Stubstad et al (US 3,867,728). Pisharodi meets the claim language as explained above, but fails to teach a coating of bioactive material as claimed. However, Stubstad teaches that it was known to use bioactive coatings to improve or prevent ingrowth; see column 11, lines 39-65. Therefore, it is the Examiner's position that it would have been obvious to put a bioactive coating on Pisharodi's device for the same reasons that Stubstad does the same.

### ***Response to Arguments***

Applicant's arguments with respect to have been considered but were considered moot in view of the new interpretation of the applied references.

***Allowable Subject Matter***

Claims 5, 25, 26, 29, 32, 33, 45, 47, 49, 50, 65, 67, 69, 71-77, 79, 82, 83, 87, 88, 96, 97, and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 120, the Examiner is interpreting the claim language as comparing one extension to another extension of the claimed elongate body.

***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic  
Primary Examiner  
Art Unit 3738